

REMARKS**I. Status of the Application**

Reconsideration of the application is respectfully requested. Claims 70, 71, 73, 75, 82-85, and 90-95 have been amended. Claims 1-68 have been canceled without prejudice or disclaimer. Therefore, claims 69-95 are currently pending and at issue.

Claim 70 has been amended to recite the acronym for scavenger receptor cysteine rich ("SRCR"), to recite "an amino acid" sequence, and to delete reference to SEQ ID NO: 7. Support for these amendments can be found throughout the specification, in particular at page 4, lines 15-17.

Claims 71, 73, 75, 90, and 95 have been amended as suggested by the Examiner. Specifically, the phrase "as depicted in" has been removed, and the claims have been amended to recite "the amino acid," support for which can be found throughout the specification, in particular at page 4, lines 15-17.

Claims 82-85 have been amended to specify "an isolated" host cell. Support for this amendment can be found in the specification at page 5, line 16, to page 6, line 1, and page 13, lines 25-28.

Claims 90 and 95 have been amended to delete reference to "equivalent" hybridization conditions. Claims 90-95 have been amended to specify oligonucleotide primers or probes. Support for this amendment can be found at page 20, lines 5-17.

No new matter has been added.

II. Rejections Under 35 U.S.C. § 101

Claims 82-85, and dependent claims 86-89, have been rejected as allegedly drawn to non-statutory subject matter. In particular, the Examiner contends that the claims do not make it clear that the cell, even though it is a recombinant cell, is an isolated cell, and therefore can read on a human being. In response, Applicants have amended claims 82-85 to specify “an isolated host cell,” as suggested by the Examiner. Therefore, Applicants submit that the rejections of claims 82-85, and dependent claims 86-89, have been overcome because isolated cells do not read on a human being. Applicants respectfully request that the rejections be withdrawn, accordingly.

III. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 73 and 75, and dependent claims 74, 76, 80, 85, and 89 have been rejected as allegedly being indefinite. Claims 73 and 75 recite the phrases “an amino acid sequence as depicted in SEQ ID NO: 2” and “a nucleotide sequence as depicted in SEQ ID NO: 1” respectively. The Examiner contends it is unclear whether the polypeptide comprises a fragment or the full length amino acid sequence of SEQ ID NO: 2, or whether the polynucleotide comprises a fragment or the full length sequence of SEQ ID NO: 1.

In response, claims 73 and 75 have been amended by replacing the term “a(n)” with “the” as suggested by the Examiner. *See* Office Action, page 3. Applicants note that these amendments do not alter the scope of the amended claims. Therefore, the rejection of claims 73-76, 80, 85, and 89 has been obviated, and Applicants respectfully request withdrawal of the rejection.

Claims 70, 73, 75, 90, and 95 and dependent claims 71, 76, 78, 80, 83, 85, 87, 89, and 91-94 have also been rejected as allegedly indefinite based on the phrases “amino acid sequence as depicted in SEQ ID NO: 2” and “nucleotide sequence as depicted in SEQ ID NO: 1.” The Examiner contends that the phrase “as depicted in” renders the claims unclear.

Claims 70, 73, 75, 90, and 95 have been amended to recite “the amino acid sequence of SEQ ID NO: 2” and “the nucleotide sequence of SEQ ID NO: 1” as suggested by the Examiner.

See Office Action, page 4. Applicants note that these amendments do not alter the scope of the amended claims. Therefore, the rejection of claims 70, 73, 75, 90, 95, and their dependent claims has been obviated, and Applicants respectfully request withdrawal of this rejection.

Claims 90-95 have been rejected as allegedly indefinite based on the phrase “hybridizes...under conditions that afford levels of hybridization equivalent to those observed under either of these two conditions.” The Examiner contends that it is not clear as to what “levels of hybridization” compared to the recited conditions are considered “equivalent.”

In response, claims 90 and 95 have been amended to remove the phrase “or under conditions that afford levels of hybridization equivalent to those observed under either of these two conditions” in order to more clearly define hybridization conditions. Therefore, the rejection of claims 90-95 has been obviated, and Applicants respectfully request withdrawal of this rejection.

IV. Rejections Under 35 U.S.C. §112, First Paragraph

(a) Written Description

Claims 90-95 have been rejected as allegedly failing to comply with the written description requirement. According to the Examiner, these claims contain new matter. Claims 90-95 are directed to “an oligonucleotide of no more than 100 nucleotides, which oligonucleotide comprises a sequence of at least 20 consecutive nucleotides of SEQ ID NO: 1” (Emphasis in Office Action). The Examiner contends that the claimed oligonucleotides were not described in the application as originally filed, or in the parent applications, and therefore the claims contain new matter. *See* Office Action, page 5.

Applicants traverse this rejection and respectfully request reconsideration.

Applicants note that the specification provides support for claims 90-95 at page 20, lines 5-8, and in original claims 18 and 19. Specifically, page 20, lines 5-8 states that “‘oligonucleotide’ refers to a nucleic acid, generally of at least 10, preferably at least 15, and more preferably at least

20 nucleotides, preferably no more than 100 nucleotides...” Originally filed claims 18 and 19 were directed to a nucleic acid of at least 20 nucleotides that hybridizes to SEQ ID NO: 1, wherein at least 10 nucleotides are contiguous nucleotides of SEQ ID NO: 1. Therefore, Applicants submit that the subject matter specified in claims 90-95 is adequately described in the specification as filed, and does not constitute new matter. Applicants respectfully request withdrawal of this rejection, accordingly.

Claims 90-95 have further been rejected as allegedly failing to comply with the written description requirement because, according to the Examiner, there is “no disclosure of any particular structure to function/activity relationship in the disclosed species.” *See* Office Action, page, 6.

Applicants traverse this rejection and respectfully request reconsideration.

Claims 90-95 have been amended to specify an isolated oligonucleotide primer or probe. Support for this amendment can be found throughout the specification, and in particular at page 20, lines 5-17.

As amended, Applicants submit that the claims are adequately described. The specification describes a novel cDNA (SEQ ID NO: 1) that encodes EER-7, a protein that demonstrates lysyl oxidase activity (*see* Specification, page 4, lines 9-14; lysyl oxidase activity is described at page 9, lines 9-19). The specification further describes that EER-7 nucleic acid sequences of various sizes can be used as labeled probes with substantial homology to SEQ ID NO: 1 (*see* page 22, lines 6-13). The specification also discloses various methods of utilizing oligonucleotide probes under high stringency conditions (*see* pages 19-20). Finally, the specification discloses that sequences homologous to EER-7 DNA fragments may not necessarily be the exact same sequence as SEQ ID NO: 1 (*see* page 22, lines 19-20). Therefore, the claimed invention is adequately described, and Applicants respectfully request withdrawal of this rejection.

(b) Enablement

Claims 70, 78, 83, 87, and 90-95 have been rejected for lack of enablement. The Examiner contends that while the specification provides enablement for polynucleotides encoding the EER-7 of SEQ ID NO: 2, it does not provide enablement for polynucleotides encoding EER-7 *further comprising* four copies of a scavenger receptor cysteine rich domain (SRCR) having at least 80% sequence identity to any one of SEQ ID NOs: 3-6. The Examiner further contends that the claims encompass polynucleotides encoding SEQ ID NO: 2 further comprising any or all fragments, mutants and recombinants of SRCR and that the specification does not provide guidance as to which amino acid residues can be modified so as to retain the claimed activity, and therefore undue experimentation is needed to make and test the claimed nucleic acid.

Applicants traverse this rejection and respectfully request reconsideration.

Claim 70 has been amended to remove the term “further” and to remove the phrase “and comprises a sequence as depicted in SEQ ID NO: 7.” As amended, claim 70 specifies a nucleic acid encoding an EER-7 protein that has an amino acid sequence which has at least about 95% sequence similarity with SEQ ID NO: 2 and lysyl oxidase activity, and also comprises four SRCR domains having a sequence at least about 80% identical to SEQ ID NOs: 3, 4, 5, and 6.

As amended, the claims do not encompass “any or all fragments, mutants, and recombinants of SRCR.” Rather, the claims only encompass those domains that have at least 80% identity to the amino acid sequences of SEQ ID NOs: 3, 4, 5, and 6, and do not alter the protein’s lysyl oxidase activity. The identification of SRCR domains having at least 80% identity to the amino acid sequence of SEQ ID NOs: 3, 4, 5, and 6, and that have lysyl oxidase activity, may be achieved by a person of skill in the art with no more than routine experimentation.

Additionally, Applicants note that claim 70 is dependent upon, and further limits, claim 69, that the Examiner has indicated is allowable (*see* Office Action, page 21). Because claim 70 further defines the claimed nucleic acid of allowable claim 69, claim 70 should also be allowable because the Examiner has indicated that the sufficient guidance has been provided such that one of

ordinary skill in the art would be able to identify the amino acids amenable to modification while retaining lysyl oxidase activity of the protein.

With respect to claims 90-95, directed to oligonucleotides, the Examiner contends that the specification does not provide enablement for oligonucleotides comprising “20-100 nucleotides, wherein the oligonucleotides comprise at least 20-30 consecutive nucleotides of SEQ ID NO: 1 and hybridizes” under the recited conditions. (*see* Office Action, page 12). The Examiner asserts that the claims are drawn to oligonucleotides having any function or unknown activity, and therefore the breadth of the claims is larger than the scope enabled by the specification (*see* Office Action, page 15).

Claims 90-95 have been amended to recite an isolated “primer or probe.” Support for this amendment can be found, for example, at page 20, lines 5-17. As amended, claims 90-95 are drawn to oligonucleotide primers or probes with well-accepted functions, as described, and the scope of the claims is within that enabled by the specification. The quantity of experimentation needed to practice the claimed invention is not excessive because a skilled artisan could readily obtain oligonucleotide primers or probes of the claimed sequence (i.e., at least 20 consecutive nucleotides of SEQ ID NO: 1 that hybridize under highly stringent conditions with a nucleic acid having the nucleotide sequence of SEQ ID NO: 1).

Therefore, because a skilled artisan could readily obtain oligonucleotide primers or probes of the sequence of claims 90-95, the instant claims satisfy the enablement requirement. Therefore, applicants request that the rejection be withdrawn, accordingly.

V. Allowable Subject Matter

The Examiner has stated that Claims 69, 72, and 77 are allowable. The Examiner stated that claim 86 would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Because claim 86 depends on claim 82, which Applicants now believe is in condition for allowance, Applicants submit that claim 86 is also in condition for allowance.

CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: September 8, 2006

Respectfully submitted,

By Amy G. Klann

Amy G. Klann, Ph.D.

Registration No.: 48,155

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant